the solution line and the red blood cell outlet line being upstream of the red blood cell pump; and

a control unit connected to the red blood cell pump and solution pump, wherein the control unit controls the flow and mixing rate of concentrated red blood cells and physiologic solution;

wherein red blood cells contained in a suspension entering the separation unit through the suspension inlet are concentrated in an annular channel of the separation unit, removed through the red blood cell outlet line, and diluted with physiologic solution.

25. (Amended) The device of claim 23, wherein the control unit controls a rate of delivery of at least one of the red blood cell pump and the solution pump so as to concentrate the red blood cells to a hematocrit of 60 to 98 percent.

## REMARKS

### I. Introduction

Claims 11 to 25 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

Applicants note with appreciation the acknowledgment that the drawings filed on August 6, 2001 are accepted.

Applicants note with appreciation the acknowledgment of the claim for foreign priority and the indication that all certified copies of the priority documents have been received in the parent application.

Applicants thank the Examiner for considering the previously filed Information Disclosure Statement, PTO-1449 paper and cited references.

### II. Objection to Claim 19

Claim 19 was objected to because the "[r]ecitation of 'selected from the group consisting of' should be followed by 'and' instead of 'or'." Office Action at page 2. Applicant has amended claim 19 as suggested by the Examiner.

Therefore, Applicant respectfully requests that the objection to claim 19 be withdrawn.

## III. Rejection of Claims 11 to 12, 16 to 17 and 19 to 25 Under 35 U.S.C. § 112

Claims 11 to 12, 16 to 17 and 19 to 25 were rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. With respect to claims 11, 12 and 19 to 22, the Office Action contends that "[these claims] are indefinite for failing to particularly point out the structural elements of a diluting device." Office Action at page 2. The Examiner will note that claim 11 has been amended to recite "the dilution device being in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution."

With respect to claims 11, 12, 21 and 22, the Office Action contends that "[r]ecitation of 'constructed and arranged' ... do not show the structural elements." Office Action at page 2. The Examiner will note that claims 11, 12, 21 and 22 have been amended to delete the recitation of the phrase "constructed and arranged."

The Office Action also contends that "[c]laims 16-17 and 25 do not show the structural element which concentrates red blood cells to the claimed hematocrit." Office Action at page 2. The Examiner will note that claims 16 and 17 have been amended to recite that " wherein the control means controls a rate of delivery of at least one of the concentrated cell pump and the solution pump so as to concentrate red blood cells to a hematocrit of 85 percent." In addition, claim 25 has been amended to recite "wherein the control unit controls a rate of delivery of at least one of the red blood cell pump and the solution pump so as to concentrate the red blood cells to a hematocrit of 60 to 98 percent."

The Office Action further contends that "[r]ecitation of 'the annular channel' in claim 23 lacks antecedent basis." Office Action at page 2. The Examiner will note that claim 23 has been amended to recite that " an annular channel of the separation unit."

In view of the foregoing, it is respectfully submitted that claims 11 to 12, 16 to 17 and 19 to 25 fully comply with the requirements of 35 U.S.C. § 112, and withdrawal of this rejection is therefore respectfully requested.

## IV. Rejection of Claims 11 to 13 and 20 to 22 Under 35 U.S.C. § 102(b)

Claims 11 to 13 and 20 to 22 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,187,979 ("Cullis et al."). Applicant respectfully submits that Cullis et al. do not anticipate the present claims for the following reasons.

Claim 11 relates to a device for processing cell suspensions for autotransfusion. Claim 11 recites that the device includes at least one separation unit for separating cells by centrifugation. Claim 11 recites that the separation unit comprises a suspension inlet line and a concentrated cell outlet line and a waste line each located downstream of the suspension inlet line. Claim 11 also recites that the concentrated cell outlet line is connected to a diluting device. Claim 11 has been amended to recite that the dilution device is in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution. Claim 11 also recites that cells contained in a suspension entering the separation unit through the ~~inlet line are concentrated in the separation unit,~~ removed through the concentrated cell outlet line, and diluted via the diluting device with a physiologic solution.

Cullis et al. purport to relate to a method and system for fractionating a quantity of blood into the components thereof. The Office Action contends that "Cullis et al teach a blood centrifugation device comprising a centrifuge (13) having a separation bag (21) comprising an inlet (38), a water line (40) and a concentrated cell outlet line (36) and a diluting device (90, 96) for diluting concentrated cells with physiologic solution wherein solution line (74) has a solution pump (78) (see figure 1; col. 4, line 58 - col. 8, line 23)." Office Action at page 3.

It is respectfully submitted that Cullis et al. do not anticipate amended claim 11 for at least the reason that Cullis et al. fail to disclose, or even suggest, a concentrated cell outlet line that is connected to a diluting device, as recited in amended claim 11. In contrast, Cullis et al. describe that "red blood cells are withdrawn from the other side corner opening [of a first separation chamber] and

returned to the container [via second conduit 58] for recirculation through the first chamber." Abstract. As shown in Figure 1, there are no connections of any kind, and certainly not of a diluting device, to the second conduit 58. Thus, Cullis et al. fail to disclose, or even suggest, a concentrated cell outlet line that is connected to a diluting device, as recited in amended claim 11

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Cullis et al. do not disclose, or even suggest, at least a concentrated cell outlet line that is connected to a diluting device, as recited in amended claim 11.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic.

Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Cullis et al. do not anticipate claim 11.

As for claims 12, 13 and 20 to 22, which ultimately depend from claim 11 and therefore include all of the limitations of claim 11, it is respectfully submitted that Cullis et al. do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 11.

## V. Rejection of Claims 11, 12 and 20 to 22 Under 35 U.S.C. § 102(b)

Claims 11, 12 and 20 to 22 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 3,655,123 ("Judson et al."). Applicant respectfully submits that Judson et al. do not anticipate the present claims for the following reasons.

The Office Action states that "Judson et al. teach a blood centrifugation device comprising a centrifuge (52) having an inlet, a waste line and a concentrated cell outlet line (36) and a diluting device (72, 76) for diluting concentrated cells with physiologic solution e.g. plasma (see figure 1; col. 7, line 29 - col. 10, line 57)." Office Action at page 3.

Judson et al. purport to disclose a continuous flow blood separator. It is respectfully submitted that Judson et al. do not anticipate claim 11 for at least the reason that Judson et al. do not disclose, or even suggest, all of the features recited in claim 11. For example, Judson et al. fail to disclose, or even suggest, a concentrated cell outlet line being connected to a diluting device, the dilution device being in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution as recited in amended claim 11. Rather, Judson et al. describe a needle rinse 72 that has valves 74 and 76 that operate to divert the flow of platelets from the centrifuge 52 to either a red blood cell line 92 or to the donor 50 (see, for example, Figure 1 and col. 8, lines 54 to 75). Thus, Judson et al. fail to disclose, or even suggest, a concentrated cell outlet line being connected to a diluting device that is in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution as recited in amended claim 11.

Therefore, for at least the reasons stated above, it is respectfully submitted that Judson et al. do not anticipate claim 11.

As for claims 12 and 20 to 22, which ultimately depend from claim 11 and therefore include all of the limitations of claim 11, is respectfully submitted that Judson et al. do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 11.

## VI. Rejection of Claim 19 Under 35 U.S.C. § 103(a)

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Cullis et al. It is respectfully submitted that Cullis et al. do not render obvious the present claims as amended herein for the following reasons.

With respect to claim 19, the Office Action contends that"[c]laim 19 essentially differs from the apparatus of Cullis et al in reciting that the separation unit has a shape selected from the group consisting of a ring or a spiral." Office Action at page 3. The Office Action concludes that "[i]t would have been an obvious matter of design choice to modify the separation unit in a shape of ring or spiral, since applicant has not disclosed that the separation unit in a shape of ring or spiral solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any other shape such as square or diamond." Office Action at page 3.

It is respectfully submitted that Cullis et al. fail to disclose, or even suggest, all of the limitations recited in claim 19. Claim 19 depends from claim 11 and therefore includes all of the limitations of claim 11. As stated above, Cullis et al. fail to disclose, or even suggest, a concentrated cell outlet line that is connected to a diluting device, as recited in amended claim 11.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir.

1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As indicated above, Cullis et al. fail to disclose, or even suggest, all of the limitations recited in claim 19, because Cullis et al. fail to disclose, or even suggest, a concentrated cell outlet line that is connected to a diluting device as recited in claim 11, from which claim 19 depends. It is therefore respectfully submitted that Cullis et al. do not render obvious claim 19.

Moreover, it is respectfully submitted that the cases of In re Fine, supra, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Office Action's generalized assertions that it would have been obvious to modify the reference do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Office Action reflects a subjective "obvious to try" standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the references relied upon. In particular, the Court in the case of In re Fine stated that:

> The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done. . . .
>
> **Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.**

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

> Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .
>
> **Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be call d evidence)**

> **that one of ordinary skill . . . would have been motivated to make th modifications . . . necessary to arrive at the claimed [invention].**

In re Jones, 21 U.S.P.Q.2d at 1943, 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art would be motivated to combine or modify the references to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for combining or modifying the references to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a "technologically simple concept" -- which is not the case here -- there still must be some finding as to the "specific understanding or principle within the knowledge of a skilled artisan" that would motivate a person having no knowledge of the claimed subject matter to "make the combination in the manner claimed," stating that:

> In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

Accordingly, there is no evidence that the references relied upon, whether taken alone or modified, would provide the features and benefits of claim 19. It is therefore respectfully submitted that claim 19 is allowable for these reasons.

## VII. Allowable Subject Matter

Applicants note with appreciation the indication of allowable subject matter contained in claims 14 to 18 and 23 to 25. Specifically, the Office Action states that "[c]laim 14-15 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim." Office Action at page 4. Applicant respectfully maintains that claims 14, 15 and 18 are in condition for immediate allowance by virtue of the amendments made herein to claim 11, from which they depend.

The Office Action also states that "[c]laims 23-25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph." Office Action at page 4. Applicant respectfully maintains that claims 23 to 25 are in condition for immediate allowance by virtue of the amendments made herein to claims 23 and 25.

The Office Action also states that "[c]laims 16-17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph ... and to include all of the limitations of the base claim and any intervening claim." Office Action at page 4. Applicant respectfully maintains that claims 16 and 17 are in condition for immediate allowance by virtue of the amendments made herein to claims 16 and 17 and by virtue of the amendments made herein to claim 11, from which they depend.

## VIII. Conclusion

Attached hereto is a marked-up version of the changes made to the Specification and claims by the current Amendment. The attached page is captioned "**Version with Markings to Show Changes Made**."

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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Dated: June 6, 2003

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PATENT TRADEMARK OFFICE

**Version with Markings to Show Changes Made**

**IN THE CLAIMS:**

Claims 11 to 13, 16 to 17, 19, 21 to 23 and 25 have been amended without prejudice as follows:

11. (Amended) A device for processing cell suspensions for autotransfusion comprising at least one separation unit [constructed and arranged to separate] for separating cells by centrifugation, the separation unit comprising a suspension inlet line and a concentrated cell outlet line and a waste line each located downstream of the suspension inlet line, the concentrated cell outlet line being connected to a diluting device, the dilution device being in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution, [constructed and arranged so that] wherein cells contained in a suspension entering the separation unit through the inlet line are concentrated in the separation unit, removed through the concentrated cell outlet line, and diluted via the diluting device with a physiologic solution.

12. (Amended) The device of claim 11, wherein [constructed and arranged so that] the remainder of the suspension separated from the cells is removed from the separation unit through the waste line.

13. (Amended) The device of claim 11, wherein the [dilution device comprises a tank containing physiologic solution, in fluid connection with the concentrated cell outlet line via a solution line, the] solution line has [having] a solution pump for controlling the flow of physiologic solution.

16. (Amended) The device of claim 15, wherein the control means controls a rate of delivery of at least one of the concentrated cell pump and the solution pump so as to concentrate [device concentrates] red blood cells to a hematocrit of 60 to 98 percent.

**Version with Markings to Show Changes Made**

17. (Amended) The device of claim 15, wherein the control means controls a rate of delivery of at least one of the concentrated cell pump and the solution pump so as to concentrate [device concentrates] red blood cells to a hematocrit of 85 percent.

19. (Amended) The device of claim 11, wherein the separation unit has a shape selected from the group consisting of a ring and [or] a spiral.

21. (Amended) The device of claim 11, wherein the device processes [constructed and arranged to process] cell suspensions collected intraoperatively.

22. (Amended) The device of claim 11, wherein the device processes [constructed and arranged to process] cell suspensions collected post-operatively.

23. (Amended) A device for processing a suspension containing red blood cells for autotransfusion comprising at least one separation unit for concentrating [constructed and arranged to concentrate] red blood cells by centrifugation, the separation unit comprising a suspension inlet connected to a suspension inlet line having a suspension pump, a red blood cell outlet connected to a red blood cell outlet line having a red blood cell pump, and a waste outlet connected to a waste outlet line;

a dilution device comprising a physiologic solution tank and a solution line having a solution pump, the solution line providing fluid connection between the physiologic solution tank and the red blood cell outlet line, the connection between the solution line and the red blood cell outlet line being upstream of the red blood cell pump; and

a control unit connected to the red blood cell pump and solution pump, wherein the control unit controls [is constructed and arranged for controlling] the flow and mixing rate of concentrated red blood cells and physiologic solution;

**Version with Markings to Show Changes Made**

wherein red blood cells contained in a suspension entering the separation unit through the suspension inlet are concentrated in an [the] annular channel of the separation unit, removed through the red blood cell outlet line, and diluted with physiologic solution.

25. (Amended) The device of claim 23, wherein the control unit controls a rate of delivery of at least one of the red blood cell pump and the solution pump so as to concentrate the red blood cells [are concentrated] to a hematocrit of 60 to 98 percent.